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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0135]

Compliance Policy Guide Sec. 420.300 Changes in Compendial Specifications and New Drug Application Supplements; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of Compliance Policy Guide (CPG) Sec. 420.300 Changes in Compendial Specifications and New Drug Application (NDA) Supplements. CPG Sec. 420.300 is included in FDA's Compliance Policy Guides Manual available on the Agency's Web site at http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm.

DATES: The withdrawal is effective August 30, 2012.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: This CPG was originally issued on October 1, 1980, in the Agency's Manual of Compliance Policy Guides. FDA is withdrawing CPG Sec. 420.300

because it is obsolete. Current guidance to FDA staff and industry regarding application requirement for changes in compendial specifications is provided in 21 CFR 314.70 and the Agency's Guidance for Industry: Changes to an Approved NDA or Abbreviated New Drug Application, which is available on the Internet at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM077097.pdf.

Dated: August 16, 2012.

Dara A. Corrigan,

Associate Commissioner for Regulatory Affairs.

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